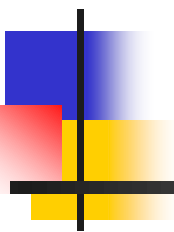


# CLIA Update - April 2015



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# Topics for Discussion

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- CMS/CLIA Laboratory Data/Statistics
  - GPRA Goal—Waived Labs
  - Glucose Meters
  - Interpretive Guidelines Update
  - Removal of CLSI Microbiology document references
  - IQCP
  - CLIA Regulations Update
  - Resources



# Current Statistics- Enrollment

<b>Total Number of Laboratories</b>	<b>250,367</b>
<b>Total Non-Exempt</b>	<b>242,262</b>
Compliance	19,793
Accredited	16,588
Waived	177,104
Provider Performed Microscopy	36,882
<b>Exempt</b>	<b>8,105</b>
NY	4,020
WA	4,085
(Source: CMS Database 1/2015)	



# Current Statistics

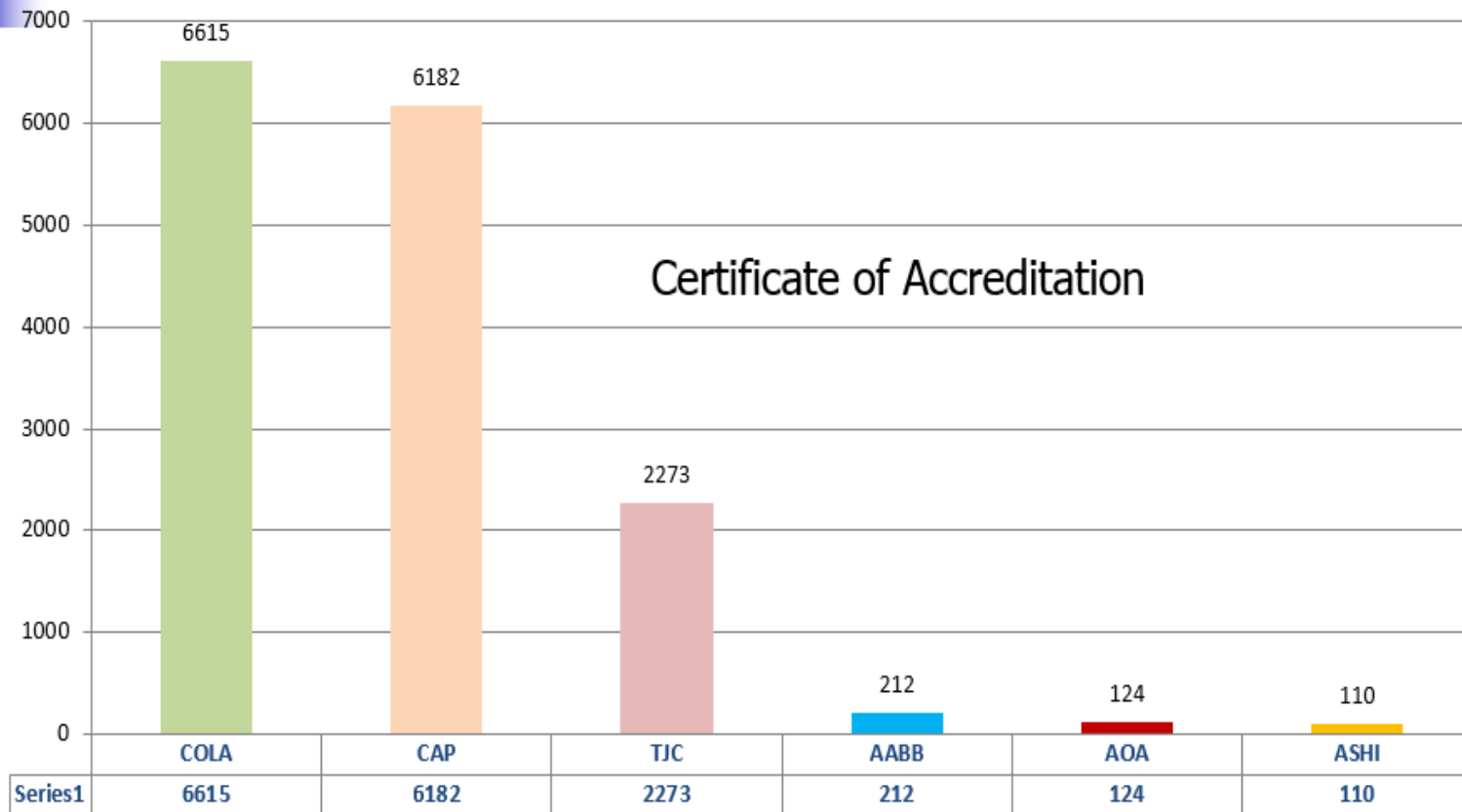
## Physician Office Laboratories by CLIA

### Certificate Type (Non-Exempt Only)

Source: CMS data base 1/2015

Waiver	61.6%
Provider Performed Microscopy	23.4%
Compliance	10.1%
Accreditation	4.9%

# CLIA COA Laboratories



# Top 10 Deficiencies

Condition Level Deficiencies	Overall Deficiencies
Moderate Complexity Lab Director Qualifications	Proper storage of reagents and specimens
Successful Proficiency Testing Participation	Analytic Systems Quality Assurance
Moderate Complexity Lab Director Qualifications	Alternative PT if no PT available
Proficiency Testing Enrollment	Procedure Manual
Analytic System QC	Test reports – patient ID
Moderate Complexity Testing Personnel	Manufacturer's Instructions
Technical Consultant qualifications	Moderate Complexity Lab Director qualifications
Hematology	Expired reagents
High Complexity Testing Personnel	Calibration verification
Technical Supervisor qualifications	Successful Proficiency Testing Participation



# Top Waived Deficiencies

Deficiency	2012	2013	2014
Not performing QC required by manufacturer	17%	16%	13%
Does not have current package insert	10%	9%	7%
Not using proper expiration date for storage method	9%	8%	7%
Not reporting patient test results as required by manufacturer	5%	5%	5%
Not following manufacturer's storage and handling instructions	5%	4%	4%



# GPRA Waived Project

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## Government Performance Review Act

- Goal - Improved compliance with CLIA Standards
- Measured by - increased percentage of Letters of Congratulations (no problems found) sent to waived (CW) laboratories based on onsite educational visits





# GPRA Waived Project

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## “Ready, Set, Test!”

- 2010 Baseline Results - 18% received Letters of Congratulations
  - Results from 2011 – 32%
  - Results from 2012 – 44%
  - Results from 2013 – 45%
  - Results from 2014 – 48%
- Conclusion: Educational materials like “Ready, Set, Test!” booklet are well-received; serve as excellent means to improve laboratory test quality.



# Glucose Meters

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- When manufacturer's instructions contain limitations indicating blood glucose monitoring systems (BGMS) have not been evaluated or cleared for use in specific patient populations such as critically ill, use of systems on these patients is considered "off-label" use.



# Glucose Meters

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- Using a test outside of FDA approved/cleared intended use, limitations or precautions as indicated in manufacturer's instructions is considered "off-label" use.
- "Off-label use" means the test (whether waived or non-waived) is considered modified and defaults to High Complexity under CLIA



# Glucose Meters

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- If the laboratory chooses to use the test “off label”, CLIA regulations at §493.1253(b)(2) require establishment of performance specifications for that test
  - Lab must also obtain a CoC or CoA
  - Lab must meet the additional CLIA requirements for high complexity testing and any applicable State regulations



# Glucose Meters

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- If CLIA surveyors note use of BGMS in a facility, they will evaluate if the system is being used per the manufacturer's instructions or "off-label"
- If any non-compliance is identified, a written statement of deficiencies will be issued to the laboratory following the Outcome Oriented Survey Process (OOSP)



# Glucose Meters-Update

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- S&C Memorandum 15-11, which was previously issued on November 21, 2014, has been withdrawn and reissued in draft-only form in order to:
  - Obtain more feedback regarding the use of waived BGMS, the environments in which BGMS are currently used, and any issues that hospitals and other providers have identified with such use
  - Promote added education regarding the current CLIA requirements



# CLIA Interpretive Guidelines

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- Revised guidelines published January 9, 2015
- Summary of major changes included with S&C:15-17-CLIA
- <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-17.pdf>



# CLIA Interpretive Guidelines

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- ***§493.15(e)***

*As with all laboratories, laboratories holding a Certificate of Waiver must follow the current manufacturer's instructions for using the waived test systems that are used in patient testing. As a part of meeting the waived testing regulatory requirements, these laboratories must comply with the manufacturer's recommendations and requirements for testing. As such, these laboratories may only use the specimen types that were approved by the Food and Drug Administration (FDA) for use with the waived test system they are using, and they must follow the manufacturer's quality control (QC) and test performance recommendations and requirements for the waived test system. Some manufacturers produce tests that can be run as a waived test or a moderate complexity test.*





# CLIA Interpretive Guidelines

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- ***§493.15(e) (cont.)***

*Any laboratory with a Certificate of Waiver that uses the nonwaived test system instructions from a manufacturer should be advised that they must use the manufacturer's instructions for waived testing. If the situation remains uncorrected, the laboratory may be cited for performing tests beyond the scope of the certificate held by the laboratory, as well as failing to follow manufacturer's instructions. See S&C-04-05.*



# Removal of CLSI Micro references

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- CLIA Interpretive Guidelines (version 05/21/04) had references to Clinical and Laboratory Standards Institute (CLSI) microbiology documents at D5477 and D5507, with additional references in CLIA S&C-09-06
- With the publication of the revised CLIA Interpretive Guidelines (01/09/15), all CLSI references have been removed from the document



# Removal of CLSI Micro references

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- Through the remainder of the IQCP Education and Transition (E&T) period, and at the end of the E&T period, microbiology laboratories will have 2 options for CLIA QC:
  - Follow all applicable CLIA QC regulations; or
  - Implement IQCP



# IQCP Facts

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- Education and transition period:
  - January 1, 2014 – December 31, 2015
- As of January 1, 2016, laboratories must be in compliance with their QC choice or deficiencies will be cited
- IQCP is optional; the default is the regulation at §493.1256(d)



# IQCP Education & Transition Period

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- CMS certified labs should:
  - Continue to following existing QC protocols
  - Decide to implement IQCP or default QC
  - Plan & complete their transition accordingly, phasing out EQC (if using it)



# IQCP Educational Outreach

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- CLIA Brochures

- Brochure 11: CLIA Individualized Quality Control Plan Introduction
- Brochure 12: Considerations when Deciding to Develop an IQCP
- Brochure 13: What is an IQCP?



# IQCP Educational Outreach

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- CMS (in collaboration w/ CDC) in final stages of development for the IQCP workbook
- Focus geared primarily towards Physician Office Laboratories (POLs) & other smaller laboratories



# CMS 2319-P: Patient Access Rule

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- Final rule publication date 02/06/14, with laboratories in compliance by 10/06/14
- Revised CLIA regulations at §493.1291(f), added new regulation at §493.1291(l)
- Amended HIPPA regulations at 45 CFR §164.524(a)(1)(i-iii)
  - Removes exceptions that relate to CLIA and CLIA-exempt laboratories
  - Aligns the Privacy Rule with the changes to the CLIA regulations





# Fecal Occult Blood (FOB) Testing

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- CMS 3271-F – Proposed rule to amend CLIA regulations by:
  - Specifying waived test categorization applies only to non-automated FOB
  - Removing hemoglobin by copper sulfate if comments confirm test is no longer used
  - This regulatory adjustment gives the FDA flexibility in categorizing FOB tests



# Updating PT Regulations

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- CMS collaborating with CDC
- Reviewing list of analytes, grading criteria and target values, etc.
- Once review is complete, publish proposed rule for public comment



# CLIA TEST Act – HR 6118

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- TEST Act – Taking Essential Steps for Testing Act of 2012
- Amendment to the CLIA statute signed by the President on 12/04/12
- Clarifies that PT samples are to be tested in the same manner as patient specimens, EXCEPT that no PT samples shall be sent to another laboratory for analysis



# CLIA TEST Act – HR 6118 (cont.)

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- Allows the Secretary enforcement discretion for:
  - Revocation of the CLIA certificate for PT referral; and
  - Imposition of the 2 year owner/operator ban when sanctioned for PT referral



# CLIA TEST Act: CMS-1443-FC

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- Regulations required to implement TEST Act changes
- Published 05/02/14, effective 07/01/14
- Final rule details hierarchical adverse actions for PT referrals by seriousness
- Defines when discretion will be applied & when revocation will be imposed
- Added definitions to §493.2 for repeat PT referral



# CMS 3267-F: Burden Rule #2

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- Final rule published 05/12/14, effective 07/11/14
- One-time narrow exception carve-out for intentional PT referral
- Clarifies intentional referral carve out with addition of the following definitions at §493.2:
  - Reflex testing
  - Confirmatory testing
  - Distributive testing



# CLIA Legislative Proposal (A-19)

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- Recommendation to change the CLIA Law to allow routine oversight of CW laboratories to ensure quality testing and facilitate patient safety
- Presented in the Summer of 2011
- Recommendation was declined



# Contact Information

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